REMARKS / ARGUMENTS

This amendment responds to the Office Action dated October 30, 2006.

Prior to this amendment, Claims 1-3, 6-25, 27, 28, 30 and 31 were pending. In this amendment, Claims 9 and 10 have been cancelled, and new claims 32, 33 and 34 have been added. Thus, claims 1-3, 6-8, 11-25, 27, 28, 30-34 are presented for further consideration, with Claims 1, 8, 13, and 31 being amended as indicated below.

Claims 1-3, 6-17, 19-25, 27, 28, 30 and 31 stand rejected as anticipated by Wetterlin (confirmed by the examiner via phone on January 29th to be US 5,983,893 to Wetterlin), and Claim 18 stands rejected as obvious over Wetterlin in view of Leedom.

Applicant thanks the examiner for his careful and thorough consideration of the present claims and the prior art of record.

This submission amends claims 1, 8, 13, and 31. Claim 1 now claims the pre-metered nature of the dose, distinguishing the claimed subject matter from the meter-in-device (non-pre-metered) device described in Wetterlin. Claim 8 has been amended to state that the covering means is a sealing flap. Claims 13 and 31 describe the pocket as blind cavity having a sole open end, and like claim 1 contain reference to the pre-metered nature of the medicament dose.

Applicant respectfully asserts that the amended claims fully comply with 35 USC 102 and 103, and therefore requests reconsideration of the claims, withdrawal of the rejections, and allowance of each of the pending claims.

In the Office Action, the Examiner maintained the objections to the independent claims based on Wetterlin. The Wetterlin reference discloses two inhaler apparatus with reference to Figures 1 and 2, respectively. The operation of the first inhaler apparatus shown in Fig. 1, operates by the user rotating the outer cylinder 4 on the inner cylinder 6. This in turn causes the manoeuvring unit 13 of the inhaler 12 (e.g. a TURBUHALER device) to rotate, through its mounting on the mounting element 24 of the outer cylinder

4, to cause a metered dose of medicament powder in the inhaler 12 to be presented at the inhalation channel of the inhaler 12. See col. 4, lines 23-27 and 32-34.

The user then telescopes the outer and inner cylinders 4,6 outwardly. This results in a negative pressure forming inside the inhaler apparatus which (i) opens the first (inlet) valve means 18 of a dispersing chamber 20, (ii) maintains a second (outlet) valve means 16 of the dispersing chamber 20 in its closed position, and (iii) draws air through air inlets 5 in the outer cylinder 4 which entrains the metered dose in the inhaler 12 into the dispersing chamber 20. The first valve means 18 then re-closes so that the metered dose is retained in the dispersing chamber 20. See col. 4, lines 34-46.

The user then either inhales on the mouthpiece 22 formed by the inner cylinder 6 to open the second valve means 16 and draw out the metered dose in the dispersing chamber for inhalation by the user (first mode of operation or "FMO"). See col. 4, lines 47-50.

Alternatively, the user telescopes the outer and inner cylinders 4, 6 back towards one another to produce a positive air pressure in the inhalation apparatus which achieves the same effect as inhalation on the mouthpiece 22 (second mode of operation or "SMO"). See col. 4, lines 51-63.

The inhaler apparatus is designed to enable the metered dose to be released to the user at lower inspiratory effort than if inhaling directly on the inhaler 12 (FMO) or without any inspiratory effort at all (SMO), in which case the user can operate the apparatus for a patient.

The operation of the second inhaler apparatus in Figure 2 is as follows. The user rotates the manoeuvring unit 13 to meter a dose of medicament powder to the inhalation channel of the inhaler 12. The user then pushes the inhaler 12 into the cylinder 6 against the bias of the spring 32 and then releases the inhaler so the spring 32 returns the inhaler 12 to its rest position, which is as shown in Fig. 2. The return movement creates the negative pressure which draws the metered dose out of the inhaler into the dispersing chamber 20, with the second (outlet) valve means 16 staying closed. The

user then inhales at the mouthpiece 22 or pushes the inhaler 12 back into the cylinder 6 to cause release of the metered dose to the user/patient, in similar manner as for Fig. 1 apparatus. See col. 4, line 64 to col. 5, line 35.

The second apparatus provides the same advantages as the first apparatus described above.

The claimed invention is not described in the Wetterlin reference. Each main claim as amended makes clear that the dose in the claimed inhaler is "pre-metered" which, as made clear in our specification at page 4, lines 16-18 means that the metering has taken place during manufacture of the inhaler, rather than in the inhaler in use. There is no clear and unambiguous disclosure in Wetterlin of a pre-metered dose in the inhaler apparatus (including the inhaler component thereof).

In the specific examples shown in Figures 1 and 2, the inhaler component has a bulk reservoir of powder from which metering takes place in use of the device. The distinction between in-use metering and "pre-metered" is also made clear in the aforementioned passage of our specification.

In addition, independent claims 13 and 31 are amended to recite that the "pocket" has *the form of a blind cavity having a solitary open end*. The Examiner considers the dispersing chamber 20 in W to be the "pocket". The Wetterlin dispersing chamber 20 has <u>two open ends</u>, top and bottom when viewed as shown in Figs 1 and 2, which are respectively covered by the first and second valve means 16, 18. This can therefore no longer be considered by the Examiner to be the "pocket" of main claims 13 and 31.

Finally, new claims 32, 33 and 34 are added to specify that the inhaler of the main claims is a unit dose inhaler. This further distinguishes from Wetterlin since Wetterlin is a multidose inhaler.

In light of this, Wetterlin does not describe each and every limitation as required to make out an anticipation rejection under 35 USC 102.

Claim 18 depends from claim 13, and is patentable for the same reasons as claim 13. Applicant has not raised any issues concerning the propriety of the proposed combination of Leedom and Wetterlin, as we believe that the amendments to the claims amply distinguish the independent claims from the references of record. Applicant does this without prejudice. We reserve the right to raise any issues associated with the patentability of dependent claims in the future as required.

For the above reasons, withdrawal of the rejection of claims 1-3, 6-8, 11-25, 27, 28, 30 and 31, and favorable consideration and a subsequent notice of allowance of each of the pending claims is respectfully requested as appropriate under these circumstances.

CONCLUSION

All issues raised by the examiner to date have been addressed. As such, the claims are asserted to be in a condition for allowance. Applicant requests that a timely Notice of Allowance be issued in this case. If any matters exist that preclude issuance of a Notice of Allowance, the examiner is requested to contact the Applicant's representative at the number indicated below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR Sections 1.16 and/or 1.17, and any necessary extension of time fees, to deposit Account No. 07-1392.

Respectfully submitted,

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